

DEC 7 2005

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
ADVIA® 2120 with Autoslide and NRBC Method

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K051693

1. Submitted By:

Andres Holle
Manager, Regulatory Affairs
Bayer HealthCare LLC
Diagnostics Division
511 Benedict Avenue
Tarrytown, NY 10591
Telephone: (914) 524-3494
FAX: (914) 524-2500
E-mail: andres.holle.b@bayer.com

2. Intended Use

The ADVIA 2120 nRBC method is intended to provide an in vitro diagnostic, quantitative determination of nucleated red blood cells in peripheral whole blood.

3. Predicate Device

Proprietary Name: Bayer ADVIA 2120 Hematology Analyzer with Autoslide
Common name: Automated Hematology Analyzer with Autoslide
Classification name: Automated hematology complete blood cell counter (§ 864.5200), differential cell counter (§ 864.5220)
Classification number: 21 CFR Parts 864.5200, 864.5220, Class II
510(k) Number: K042251

nRBC counts are performed by manual methods that are well established as reference methods in clinical laboratories and consistent with NCCLS H-20A.

4. Device Information

Proprietary Name: Bayer ADVIA 2120 Hematology Analyzer with Autoslide System
Common name: Automated Hematology Analyzer and Automated Slide Maker and Stainer
Classification name: Automated hematology complete blood cell counter (§ 864.5200),
differential cell counter (§ 864.5220) and automated slide stainer (§ 864.3800)
Classification number: 21 CFR Parts 864.5200, 864.5220, 864.3800 , Class II

The only change between the predicate device and the new device is the introduction of a new method for nucleated red blood cell analysis.

5. Device Description

The technological and methodological principles of the ADVIA 2120 with Autoslide used for the quantitative measurement of blood cells in whole blood specimens will be used without change except for the addition of a new methodology to quantitate nucleated red blood cells and correct for white blood cells in peripheral whole blood.

The ADVIA 2120 Nucleated Red Blood Cell (nRBC) method is described below:

- a) The ADVIA 2120 nRBC Analysis method uses histogram analysis routines to analyze the unstained region of the Peroxidase channel as well as an arithmetic algorithm that combines counts from the Peroxidase and Basophil/Lobularity channels to enumerate nRBCs.
- b) The analysis corrects the White Blood Cell Count for the presence of nRBCs, as well as the WBC Differential. It reports the corrected WBC count and the corrected differential.

The new nRBC method will report the following Red Blood Cell Parameters-

- 1) % nucleated Red Blood Cells (% nRBC)
- 2) absolute nRBC (# of nRBC per microliter)

6. Summary of Technological Characteristics

Nucleated red blood cells (nRBCs, erythroblasts, normoblasts, or normocytes) are immature red blood cells that are normally found only in the bone marrow of healthy adults. Cells of this stage are usually observed in the peripheral blood of newborn infants or in patients with responses to hemolytic crisis.

The presence of nRBCs in peripheral blood can falsely elevate the WBC count in automated hematology analyzers and interfere with the accuracy of the automated WBC differential.

The ADVIA 2120 nRBC method reports nRBC counts for whole blood samples with either 200 or more nRBC/ μ L, or with at least 2% nRBCs with a WBC count of at least 3,000/ μ L.

The method reports both an absolute nRBC count (10^9 /L) and a percentage count (#NRBC/100 WBC). The software also corrects the WBC count for nRBC, recalculates the WBC differential, and recalculates %MN and %PMN.

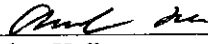
The method identifies nRBCs by nuclear size in the peroxidase negative area of the Peroxidase channel, and by nuclear density and volume in the Basophil/Lobularity channel.

In the unstained region of the Peroxidase channel cytogram, nRBC nuclei are located between the noise and lymphocytes. They often form distinct populations that are analyzed to produce counts.

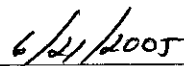
In the Basophil/Lobularity channel cytogram, nRBC nuclei are located in the polymorphonuclear region, rather than the mononuclear region, because they are denser than lymphocyte or monocyte nuclei. Since they are not the nuclei of polymorphonuclear cells, the difference between the number of nuclei in this region and the sum of neutrophils and eosinophils in the Peroxidase channel may equal the nRBC count.

7. Conclusion

The information and performance data provided as part of this submission demonstrate that the nRBC method on the ADVIA 2120 with Autoslide is substantially equivalent to products already in commercial distribution



Andres Holle
Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097



Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Mr. Andres Holle
Manager, Regulatory Affairs
Bayer HealthCare LLC
Diagnostics Division
511 Benedict Avenue
Tarrytown, New York 10591

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 7 2005

Re: k051693
Trade/Device Name: ADVIA® 2120 with nRBC Method
Regulation Number: 21 CFR § 864.5200
Regulation Name: Automated cell counter
Regulatory Class: II
Product Code: GKL, GKZ, KPA
Dated: October 26, 2005
Received: October 27, 2005

Dear Mr. Holle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

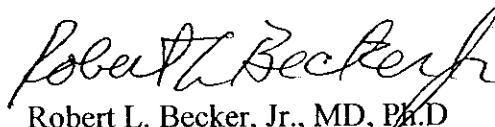
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,

A handwritten signature in cursive script, reading "Robert L. Becker, Jr.", written in dark ink.

Robert L. Becker, Jr., MD, Ph.D

Director

Division of Immunology and Hematology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051693

Device Name: ADVIA® 2120 with nRBC Method

Indications For Use:

The ADVIA® 2120 Nucleated Red Blood Cell (nRBC) method is intended to provide an *in vitro* diagnostic, quantitative determination of nucleated red blood cells in peripheral whole blood.

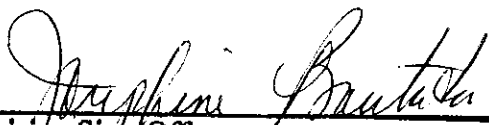
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off

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Office of In Vitro Diagnostic Device
Evaluation and Safety

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